REMARKS

The Amendments

The claims are replaced with new claims to more particularly recite the invention.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 1-3, 5-12, 14 and 17 under 35 U.S.C. §112, first paragraph, is respectfully traversed.

The claims are narrower in scope than those subject to this rejection in the Final Office Action. Since the rejection was, at least partly, based on an alleged overbreadth of scope of the claims, it is believed the rejection may be rendered moot in view of the new claims. However, the following additional remarks are provided to supplement the arguments already of record.

The current independent claim recites that a controlled release formulation is administered to a patient by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively eliminated or reduced and that the formulation comprises a substance which eliminates or prevents formation of the cells of adipose tissue provided in a controlled release carrier. The literal scope of the claim is thus

quite specific in reciting the manner of administration, the location of administration and the effect of the treatment. Regarding the active agent, there is literal specificity in its form as being in a controlled release carrier and in its resulting effect. Although, the active may be selected from a genus of actives which eliminate or prevent formation of the cells of adipose tissue, the specification gives ample guidance for one of ordinary skill in the art to select such active substances; see, e.g., page 4, second paragraph, of the instant specification providing a detailed list of representative substances for this effect and guidance to one of ordinary skill in the art in selecting suitable substances. Further, even outside applicants' disclosure, substances which eliminate or prevent formation of the cells of adipose tissue are well known to those of ordinary skill in the art. In view of this knowledge together with the guidance provided by the specification, one of ordinary skill in the art would readily be able to select active substances with such effect. Thus, the instant claimed invention, in this scope, is clearly adequately described to one of ordinary skill in the art by applicants' disclosure.

To the extent that the substance used in the claimed method may encompass as yet undiscovered substances which eliminate or prevent formation of the cells of adipose tissue, such does not direct against adequate written description. As Judge Rich stated in *In re Durden Jr.*, 226 USPQ 359, 362 (Fed. Cir. 1985), "A process, after all, is a manipulation according to an algorithm, as we have learned in recent years - doing something to or with something according to a schema." A process invention has as its thrust the "manipulation" of a thing. The nature of that thing is of no import as long as it is amenable to the manipulation. The process may even be applicable to things that are yet to be discovered and still be the same process. As such, more precise definition of the reactants involved is not necessary to provide a complete and definite description of the invention herein under 35 U.S.C. §112. The situation is analogous here, the process is using known elements in a new

way.

Additionally, the PTO has provided no proof that the invention is in an unpredictable art area and the knowledge in the art of drugs for eliminating or reducing normal but undesired tissue belies such a position. Contrary to the statements in the Final Office Action, applicants' argument pertained to lack of proof of an unpredictable art area, not lack of proof of operability. Absent any proof of unpredictability or evidence of reason to doubt the truth of applicants' disclosure, the PTO's burden of proof to support a 35 U.S.C. §112, first paragraph, rejection is not met. Applicants' disclosure reasonably describes the result of the method and the means to accomplish the result in general terms and also provides sufficient representative examples of both the result and the formulations for achieving it. Further, numerous examples of the drugs and of controlled release formulations for achieving such result were known in the art. Applicants need not describe that which is well known in the art to meet the 35 U.S.C. §112, first paragraph, requirements.

For the above reasons, applicants respectfully submit that the instant claims have adequate written description and the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Rejection under 35 U.S.C. §102

The rejection of claims 1-3, 5, 6, 9-12, 14 and 17 under 35 U.S.C. §102, as being anticipated by Goldenberg (WO 98/46211) is respectfully traversed.

Goldenberg discloses only methods wherein the patient is subject to a general effect by the drug. For example, in all the embodiments referring to Goldenberg's anti-obesity methods, the results are discussed in terms of overall weight of the patient (or animal model, see, e.g, page 22) and not in terms of the loss of tissue in any particular local area,

particularly not in the local area into which the drug is administered. Although Goldenberg does provide a generically recited long list of possible administration routes (see, e.g., pages 12-13), it does not provide any disclosure that such injection results in elimination or reduction of the normal but undesired tissue in the local area of the injection. Although it is likely true that Goldenberg's systemic treatment for a general effect has the incidental result that the tissue (e.g., fat) is reduced in the area of the injection to the same extent as the rest of the body, such incidental result does not meet the terms of applicants' claims, i.e., "undesired adipose tissue in the local area is **selectively** eliminated or reduced." There is no disclosure or suggestion from Goldenberg that elimination or reduction in tissue occurs in the local area of the injection exclusively or to a significantly higher degree than other areas of the body not subject to the injection, i.e., it occurs "selectively" at the local area of administration.

Applicants' disclosure gives ample guidance as to the meaning of the "local area" and the selective effect thereon which is consistent with the art-recognized meaning. The specification distinguishes the inventive local administration with selective effect from general administration with systemic effect in the Background section of the specification. Also in the Background, it points out other art which utilizes local administration methods for different effects. Thus, it is clear that local administration and selective effect are terms used in the art having a defined meaning. Further, the specification gives representative examples of specific types of administration to achieve the local area selective effect (see, e.g., page 6, third full paragraph, and paragraph bridging pages 6-7). Finally, the specification provides in vivo and in vitro examples with rat models demonstrating specific applications of the method and showing their selective localized effect (see pages 8-18 of the specification).

In view of this correct interpretation of the "local area" and "selective" terms in the claims, it is again strongly urged that Goldenberg does not disclose a method wherein a

sustained-release formulation is administered to the patient "by injection into the adipose tissue at a local area such that undesired adipose tissue in the local area is selectively eliminated or reduced." Goldenberg discloses only a general, systemic treatment and does not meet the correctly defined "local area" effect recited in the instant claims.

Additionally, Goldenberg provide no specific disclosure of any method involving administration of a substance by "injection into the adipose tissue." Compare current claim 33. All of the Goldenberg examples involve subcutaneous administration, i.e., under the skin, and no disclosure or suggestion of injection into adipose tissue. Even the laundry list of generic administration methods at pages 12-13 of Goldenberg provides no specific direction to one of ordinary skill in the art towards administration by injection into adipose tissue. For this additional reason, alone, the rejection under 35 U.S.C. §102 should be withdrawn because Goldenberg provides no specific teaching that it was in possession of a method meeting this element of the claims.

For all of the above reasons, Goldenberg cannot anticipate the instant claims and the rejection under 35 U.S.C. §102 should be withdrawn.

The Rejections under 35 U.S.C. §103

The rejections of the claims under 35 U.S.C. §103, as being obvious over Goldenberg, alone, or in view of the Hutchinson, Ogawa or Johnson articles, Silvestri (U.S. Patent No. 5,126,147), or Silvestri, further in view of the Merwin article, are respectfully traversed.

The discussion of Goldenberg above in connection with the traversal of the 35 U.S.C. §102 rejection is incorporated herein by reference. To summarize, Goldenberg fails to disclose a method wherein the controlled release formulation is injected into "adipose tissue at a local area such that undesired adipose tissue in the local area is selectively eliminated or

reduced." It also fails to disclose a method involving administration by "injection into the adipose tissue." Applicants urge that Goldenberg also fails to suggest modifying its method to meet the elements of the instant claims.

Goldenberg provides no teachings which give any hint to one of ordinary skill in the art that a controlled release formulation could be injected into adipose tissue at a local area to eliminate or reduce the adipose tissue selectively in that local area. To the contrary, all the teachings in Goldenberg relate to administration of a sustained-release formulation to achieve general/systemic effects on the patient, for example, overall weight loss. Similarly, all of the secondary references also relate only to systemic delivery of drugs to achieve a general effect. There is no suggestion in any of the references that a specific local area of adipose tissue could be targeted by injection directly into the adipose tissue and that selective reduction of the adipose tissue in that local area could be achieved, as opposed to a systemic effect. A general weight loss effect taught by the art suggests to one of ordinary skill in the art that the weight loss is relatively evenly distributed in the patient and, thus, is not suggestive of the elimination or reduction of adipose tissue targeted to the local area of injection.

Further, there is no suggestion from any of the secondary references for administration by "injection into the adipose tissue."

For the above reasons, it is urged that no combination of the cited art renders the claimed invention obvious to one of ordinary skill in the art. Thus, the rejections under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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